

CLAIMS

We claim:

1. A hinge having a variable center of rotation comprising:
 - a. an inner shell, a middle shell, and an outer shell, said middle shell rotatably engaged to said inner shell and having an inner-middle shell co-axis and middle shell rotation whereby said middle shell rotates relative to said inner shell, and said outer shell rotatably engaged to said middle shell and having a middle-outer shell co-axis and outer shell rotation whereby said outer shell rotates relative to said middle shell, wherein said inner shell does not rotate, and wherein said inner-middle shell co-axis is located at the center of the inner shell, and said middle-outer shell co-axis is located off-center of said middle shell;
 - b. said inner shell further comprising an inner shell protuberance;
 - c. said middle shell further comprising a middle shell protuberance, and a middle shell slot through which said inner shell protuberance tracks, wherein said inner shell protuberance tracking constrains said middle shell rotation of said middle shell relative to said inner shell;
 - d. said outer shell further comprising an outer shell slot through which said middle shell protuberance tracks, wherein said middle shell protuberance tracking constrains said outer shell rotation of said outer shell relative to said middle shell;
 - e. a motion constraining element to prevent rotation of said middle shell relative to said inner shell over a first flexion range as said outer shell rotates relative to said middle shell over said first flexion range and to prevent rotation of said outer shell relative to said middle shell over a second flexion range as said middle shell rotates relative to said inner shell, wherein said second flexion range does not overlap said first flexion range.
2. The hinge of claim 1, wherein the motion constraining element comprises:
 - a. the outer shell further comprising an outer shell protuberance;
 - b. a cover shell, wherein said cover shell comprises a cover shell slot through which said outer shell protuberance tracks;
 - c. wherein said cover shell slot is shaped so that over said first flexion range said cover shell slot has the shape of said outer shell slot and over said

second flexion range said cover shell slot has the shape of said middle shell slot.

3. The hinge of claim 1 wherein the middle shell has an outer edge and the motion constraining element comprises:
 - a. a bulb operably connected to the outer edge of the middle shell wherein the bulb further comprises
 - i. a stem having two ends, the first end rotatably connected to the outer edge of the middle shell;
 - ii. four orthogonal arms comprising a first pair of arms and a second pair of arms, wherein the arms are non-rotatably connected to the stem's second end, wherein
 1. the first pair of arms engage with one of the inner and outer shells thereby preventing rotation of the middle shell relative to one of the inner and outer shells, and
 2. the second pair of arms receive a force from one of the inner and outer shells thereby rotating the bulb in a ninety degree increment.
4. The hinge of any of claims 1 - 3 wherein:
 - a. said outer shell slot is an arc of approximately 30 degrees of a notional circle having a radius of curvature of between approximately 5 mm to 17 mm, wherein said outer shell slot is positioned anterior to the middle-outer shell co-axis, so that during said first flexion range the center of rotation location varies with flexion, said location constrained by said tracking of said middle shell protuberance with said outer shell slot;
 - b. said middle shell slot is an arc of approximately 120 degrees of a notional circle positioned posterior to said inner-middle shell co-axis, when flexion is thirty degrees or less, having a radius of curvature of between approximately 5 mm to 17 mm, so that during said second flexion range the center of rotation location does not vary.
5. The hinge of any of claims 1 - 3 wherein:
 - a. said outer shell slot is an arc of approximately 60 degrees of a notional circle positioned anterior to the middle-outer shell co-axis having a radius of curvature of between approximately 5 mm to 17 mm, so that during said first flexion range the center of rotation location varies with flexion, said location

- constrained by said tracking of said middle shell protuberance with said outer shell slot;
- b. said middle shell slot is an arc of approximately 90 degrees of a notional circle positioned proximal to said inner-middle shell co-axis upon extension, having a radius of curvature of between approximately 5 mm to 17 mm, so that during said second flexion range the center of rotation location varies with flexion.
6. The hinge of any of claims 1 - 3 wherein:
- a. said outer shell slot is an arc of approximately 60 degrees of a notional circle positioned distal to said middle-outer shell co-axis, upon extension, having a radius of curvature of between approximately 5 mm to 17 mm, so that during said first flexion range the center of rotation location varies with flexion, said location constrained by said tracking of said middle shell protuberance with said outer shell slot;
- b. said middle shell slot is an arc of approximately 90 degrees of a notional circle positioned posterior to said inner-middle shell co-axis, upon extension, having a radius of curvature of between approximately 5 mm to 17 mm, so that during said second flexion range the center of rotation location varies with flexion, said location constrained by the tracking of the inner shell protuberance with the middle shell slot.
7. A hinge comprising:
- a. an inner shell, a middle shell, an outer shell, and a cover shell, said middle shell rotatably engaged to said inner shell and having an inner-middle shell co-axis and middle shell rotation, said outer shell rotatably engaged to said middle shell and having a middle-outer shell co-axis and outer shell rotation, wherein said inner shell and cover shell do not rotate, and wherein said inner-middle shell co-axis is located at the center of the inner shell, and said middle-outer shell co-axis is located off-center of said middle shell;
- b. said inner shell further comprising an inner shell protuberance;
- c. said middle shell further comprising a middle shell protuberance, and a middle shell slot through which said inner shell protuberance tracks, wherein said inner shell protuberance tracking constrains said middle shell rotation of said middle shell relative to said inner shell;
- d. said outer shell further comprising an outer shell protuberance and an outer shell slot through which said middle shell protuberance tracks, wherein said

- middle shell protuberance tracking constrains said outer shell rotation of said outer shell relative to said middle shell;
- e. said cover shell further comprising a cover shell slot through which said outer shell protuberance tracks, wherein said cover shell slot is shaped so that over said first flexion range said cover shell slot has the shape of said outer shell slot and over said second flexion range said cover shell slot has the shape of said middle shell slot;
 - f. said cover shell and said inner shell connected to a femoral arm.
8. A knee brace comprising one or two of the hinges of any of claims 1 - 7.
9. The knee brace of claim 8 further comprising:
- a. a thigh cuff having a medial portion, a lateral portion and an anterior portion;
 - b. a tibial cuff having a medial portion, a lateral portion and an anterior portion;
 - c. a proximal lateral arm linked to the lateral portion of said thigh cuff;
 - d. a proximal medial arm linked to the medial portion of said thigh cuff;
 - e. a distal lateral arm linked to the lateral portion of said tibial cuff;
 - f. a distal medial arm linked to the medial portion of said tibial cuff;
 - g. a lateral hinge for linking said proximal lateral arm to said distal lateral arm;
 - h. a medial hinge for linking said proximal medial arm to said distal medial arm;
 - i. a posterior proximal belt linking said proximal lateral arm to said proximal medial arm;
 - j. a posterior distal belt linking said distal lateral arm to said distal medial arm;
 - k. means to secure said thigh cuff to a wearer's thigh;
 - l. means to secure said tibial cuff to a wearer's tibial shank.
10. The knee brace of claim 9 for correcting a varus knee wherein said lateral hinge is any one of the knee hinges of claims 1 - 4 and 7 and wherein said medial hinge is any one of the knee hinges of claims 1 - 3, 5 and 7 wherein simultaneous motion of the lateral hinge and the medial hinge during flexion generate an unloading force on the medial compartment of the varus knee during extension between about 0 degrees and about 30 degrees of flexion and an internal rotation on the tibia during flexion.
11. The knee brace of claim 8 for correcting a valgus knee wherein said medial hinge is any one of the knee hinges of claims 1 - 4, and 7 and wherein said lateral hinge is any one of the knee hinges of claims 1 - 3, 6 and 7, wherein simultaneous motion of

the lateral hinge and the medial hinge during flexion generate an unloading force on the lateral compartment of the valgus knee during extension between about 0 degrees and about 30 degrees of flexion and an internal rotation on the tibia during flexion.

12. The knee brace of any of claims 8 - 11 wherein the thigh and tibial cuff securing means comprise a fastenable elastic belt.
13. A method for treating a knee pathology comprising:
 - a. altering an abnormal rotation of the tibia, wherein said altering involves applying a rotational force to the tibia during flexion in a direction opposite to that of said abnormal rotation, and
 - b. applying an off-loading force to the knee, wherein said rotational force and said off-loading force is applied repeatedly during every flexion/extension cycle so as to correct the knee pathology.
14. The method of claim 13 wherein said application of rotational force and off-loading force is generated by a combination of a first hinge and a second hinge, the first hinge located medial to the knee and the second hinge located lateral to the knee, wherein said first hinge has a first variable center of rotation and said second hinge has a second variable center of rotation.
15. The method of claim 14 wherein:
 - a. the first variable center of rotation is defined by tracking of a middle shell protuberance in the medial hinge with an outer shell slot in the medial hinge over a first flexion range, and tracking of an inner shell protuberance in the medial hinge with a middle shell slot in the medial hinge over a second flexion range; and
 - b. the second variable center of rotation is defined by tracking of a middle shell protuberance in the lateral hinge with an outer shell slot in the lateral hinge over a third flexion range, and tracking of an inner shell protuberance in the lateral hinge with a middle shell slot in the lateral hinge over a fourth flexion range.
16. The method of claim 15 for correcting a varus knee wherein the rotational force is generated by locating the first variable center of rotation of the medial hinge distal to the cylindrical axis generating a distraction force on the femur in extension during the

first flexion range, and locating the center of rotation of the lateral hinge proximal to the cylindrical axis during the third flexion range, thereby correcting varus knee malalignment.

17. The method of claim 15 for correcting a valgus knee wherein the rotational force is generated by locating the center of rotation of the lateral hinge distal to the cylindrical axis during the third flexion range, and locating the center of rotation of the medial hinge proximal to the cylindrical axis during the first flexion range, thereby correcting valgus knee malalignment.
18. The method of any of claims 13 - 17 wherein said knee is an osteoarthritic or osteoarthritic-prone knee.
19. A method for treating a knee pathology using any of the devices of claims 1-12.
20. The method of claim 19 wherein said knee pathology is an osteoarthritic or osteoarthritic-prone knee.